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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/600,118

06/20/2003

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

07/14/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/600,118

**Applicant(s)**

CIMINO, WILLIAM W.

**Examiner**

LAURA BOUCHELLE

**Art Unit**

3763

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-6,8-12,14,15,17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8-12,14,15,17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/10/11.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/11/11 has been entered.

### ***Response to Amendment***

2. The Declaration under 37 CFR 1.132 filed 3/12/11 by Daniel S. Goldberger is insufficient to overcome the previous rejection as set forth in the last Office action because: Mr. Goldberger states that he believes that the described and claimed invention is the first device available to the market that can precisely monitor rapid fluid flow for aesthetic medical procedures. This argument does not support the non-obviousness of the invention because the lack of a product on the market has no bearing on the patentability of that invention.

3. The Declaration under 37 CFR 1.132 filed 2/11/11 by Dr. Mark L. Jewell, M.D. is insufficient to overcome the previous rejection as set forth in the last Office action because: Dr. Jewell states that he is unaware of any device that could deliver fluid rapidly and precisely for use in aesthetic procedures prior to the instant invention. This argument is not convincing because the lack of a product on the market has no bearing on the patentability of that invention. Dr. Jewell also states that the instant invention fulfills a long felt need in the industry. The Examiner has not found enough evidence to support this assertion. In order to show that the invention satisfies a long felt need, objective evidence that a recognized problem existed in the

art for a long period of time without solution must be presented. The Examiner recognizes that there is a need to measure the amount of fluid delivered as is evidenced by the journal article submitted with the declaration. However, the declaration does not provide evidence that this need has not been previously met. Maddock discloses that the pumping system used for filling mammary prostheses includes volume measuring capabilities (abstract).

***Response to Arguments***

4. Applicant's arguments filed 2/22/11 have been fully considered.
5. Applicant's arguments with regard to Ruiz have been considered and are convincing.
6. Applicant's arguments with respect to Wheeldon have been considered and are not convincing. Applicant argues that Wheeldon discloses a device for intravenous infusion and one of skill in the art would not look to an intravenous delivery system to modify a device for filling a mammary prosthesis. The examiner disagrees. The relevant art is medical fluid delivery pumps. One of skill in the art would recognize that delivery devices for any type of fluid are known and that it is common for pumps intended for different procedures have similar components.
7. As discussed above, the Declaration submitted by Dr. Jewell does not establish a long felt need in the art. The declaration asserts Dr. Jewell's opinion that the claimed invention is better than previously used devices and methods, but does not provide evidence of a long felt need (see MPEP 716.04).
8. It is also noted that the declarations speak specifically to methods and devices for UAL and breast augmentation, whereas the independent claims recite a system and method for delivery of desired volume of fluid to a targeted anatomical site *or* a device in a cosmetic surgery

procedure. The claims and the arguments presented in the declaration are not commensurate in scope and therefore, the declaration can not render the invention non-obvious.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 10 preamble recites a method for delivering fluid “to a targeted anatomical site or an device in a cosmetic surgery procedure”, line 13 recites tubing for delivery to the cosmetic surgery procedure, line 15 recites includes the step of activating the pump to deliver fluid to a targeted anatomical site or the device, and the last line of the claim recites that the pump is stopped when the desired amount of fluid has been provided "for the cosmetic surgery procedure". It is unclear if the scope of the claim includes a method of delivery to a target anatomical site or a cosmetic surgery device or just the cosmetic surgery.

***Claim Rejections - 35 USC § 103***

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. Claims 1, 2, 4, 6, 9, 10, 11, 15, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savage et al (US 6,319,221) in view of Ognier et al (US 5,178,606).

14. Savage discloses a system for rapidly delivering and accurately monitoring the delivery of a desired volume of sterile fluid to a targeted anatomical site comprising a strain gauge sensor 108, a container of sterile fluid 12 connected to the strain gauge sensor so that the sensor will generate an electrical output proportional to the weight of the fluid in the container (col. 3, lines 42-46), a pump 306 for rapidly pumping the desired amount of fluid to the site (col. 10, lines 64-67), a sterile tubing set, a processor 24 for processing the electrical output from the strain gauge to determine the volume of fluid delivered during the procedure (col. 4, lines 43-45), the processor is not electrically connected to the pump (see fig. 9), and a display 64 for displaying the amount of fluid delivered (col. 6, lines 52-55).

15. Savage also discloses a method for delivering and monitoring the delivery of a desired volume of fluid to a targeted anatomical site comprising the steps of providing the invention described above. Savage discloses that an end of the tubing is made available for delivery of sterile fluid to any location within the body. The processor can determine the volume of fluid removed from the container regardless of the rate of removal of fluid because the strain gauge measure the weight of the fluid which is independent of the rate of flow into or out of the container.

16. Regarding claims 1, 10, Savage discloses that the device typically operates at flow rates of more than 500 ml/min (col. 1, lines 49-50) and that the device is capable of delivering indefinite amounts of fluid due to the capability of the device to allow empty containers to be replaced with full containers (col. 7, lines 29-33), but fails to disclose a peristaltic pump that is adjustable by a user within the claimed range. Ognier teaches an irrigation and aspiration

apparatus for use in an endoscopic surgery procedure comprising a peristaltic pump for delivering sterile fluid to the patient, the pump is adjustable to deliver fluid at rates of 0 to 700 ml/min (col. 3, line 65 - col. 4, line 4). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Savage to include a peristaltic pump as taught by Ognier so that the device can meet the requirements for use in a variety of procedures. A versatile device is desirable because using one pump for multiple types of procedures reduces the number of devices a hospital must purchase.

17. Regarding claim 10, Savage fails to disclose that the pump is stopped when the desired volume has been delivered. It would have been obvious to one of ordinary skill in the art at the time of invention to discontinue the delivery of fluid when the desired fluid is delivered because the purpose of monitoring the amount of fluid delivered is to determine when the desired amount of fluid has been delivered.

18. Regarding claim 2, the device of Savage in view of Ognier is capable of being used in a lipoplasty or a breast implant procedure because it delivers fluid to a site within the body at a controlled rate.

19. Regarding claims 4, 6, 9, 15, 18, Savage discloses a reset button that will zero the display (col. 8, lines 1-3). The amount of fluid is displayed in volume (col. 6, lines 57-60).

20. Claims 5, 8, , 14, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savage in view of Ognier as applied to claims 1, 10 above, and further in view of Dunberger et al (US 5,399,160). Savage and Ognier fail to disclose that the tubing is formed from PVC. Dunberger teaches a irrigation tubing set wherein the tubing is formed from PVC. PVC is

commonly used in medical tubing because it is biocompatible, flexible and sterilizable. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Savage in view of Ognier to include tubing formed from PVC as taught by Dunberger because PVC is a commonly used material in the medical arts because of its flexibility, biocompatibility and ability to be sterilized.

21. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Savage in view of Ognier as applied to claims 1, 10 above, and further in view of Maddock et al (US 5,549,672). Savage and Ognier do not disclose the step of using the device to perform a cosmetic procedure consisting of lipoplasty and the filling of breast implants or sizers. Maddock teaches that a system comprising a pump having fluid measuring capabilities can be used to fill breast implants (abstract). Such a system is desirable because it allows the user to focus on the injection instead of having to concentrate on the amount of fluid being delivered (abstract). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Savage in view of Ognier to use the device to fill a breast implant as taught by Maddock because an accurate and user friendly methods of determine delivered fluid volume is necessary when filling a breast implant and that is what the device of Savage provides.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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